UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GOJO INDUSTRIES, INC.,

Plaintiff,

-against-

INNOVATIVE BIODEFENSE, INC. and AQUARIUS GLOBAL ENERGY PARTNERS, LLC

Defendants.

OPINION & ORDER

15 Civ. 2946 (PAC)

HONORABLE PAUL A. CROTTY, United States District Judge:

Plaintiff GOJO Industries, Inc. ("GOJO") moves to stay the action it commenced pending resolution of a regulatory enforcement action brought by the Food and Drug Administration ("FDA") and the Department of Justice ("DOJ") against Defendant Innovative Biodefense, Inc. ("IBD") and its President Colette Cozean. The Court DENIES Plaintiff's motion.

BACKGROUND

GOJO and IBD[1] manufacture competing hand hygiene products. GOJO claims that IBD engaged in false advertising and deceptive business practices by representing that IBD's Zylast hand sanitizing products are "FDA approved"; and using the FDA logo in its advertising, in violation of the Lanham Act, 15 U.S.C. § 1125(a), and New York general business law. Compl., Dkt. 1. GOJO also alleges that IBD made false and misleading representations to customers about alcohol-based sanitizers, including GOJO's Purell hand sanitizing product. *Id.* IBD counterclaims, alleging that GOJO itself engaged in false advertising and deceptive business practices by falsely

[1] Defendant Aquarius Global Energy Partners, LLC was dismissed from this action after agreeing to and complying with the terms of a Stipulation and Order of Permanent Injunction entered on April 24, 2015. (*See* Dkts. 28 & 47).

claiming Purell is "FDA approved" and/or compliant with the FDA's Tentative Final Monograph for Healthcare Antiseptics, using logos from various international health organizations without their consent, and deliberately designing studies that favor Purell products, in violation of the Lanham Act and California law. Ans. & Counterclaim, Dkt. 51. IBD also accuses GOJO of making false or misleading statements about its Zylast sanitizers, including that Zylast products do not comply with FDA regulations. *Id.*

GOJO commenced this lawsuit on April 15, 2015. Compl., Dkt. 1. This lawsuit has lumbered into its fifth year, beset by various discovery disputes and an unsuccessful attempt at mediation. The parties recently agreed to a deadline of October 17, 2019 for the completion of expert depositions; and January 6, 2020 for dispositive motions. *See* Dkt. 238.

The FDA Action

On June 6, 2018, the United States[2] filed a regulatory enforcement action against IBD and Cozean (the "FDA Action") in the U.S. District Court for the Central District of California. Greenfelder Dec., Dkt. 223, Ex. 3. The Government alleges in its Amended Complaint, filed on August 27, 2018, that IBD's Zylast products violate 21 U.S.C. § 331(d) of the Food, Drug, and Cosmetic Act ("FDCA") because they meet the statute's definition for a "new drug" but were sold without the requisite new drug application, abbreviated new drug application, or investigational new drug application. *Id.* at 6-9. The Government seeks only prospective relief; enjoining IBD and Cozean from continuing to introduce the Zylast products into interstate commerce until they have removed all statements from their labeling which allegedly cause them to be "new drugs" as

[2] The FDCA specifically authorizes federal district courts to issue injunctions to prevent violations of the Act. 21 U.S.C. § 332. Since the FDA does not have independent litigating authority, injunction suits are filed on behalf of the U.S. Government in cooperation with DOJ. *See generally* FDA Regulatory Procedures Manual, Ch.6-2-4 (2015), available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual.

defined in the FDCA. *Id.* at 10.

IBD and Cozean moved to dismiss the Government's Amended Complaint on September 17, 2018. Greenfelder Dec. Ex. 4. On February 22, 2019, U. S. District Judge David O. Carter denied the motion. Greenfelder Supp. Dec., Dkt. 232, Ex. 9. Following denial, the parties agreed to a deadline of July 30, 2019 for fact and expert discovery, a deadline of October 21, 2019 for motion cut-off, and a trial date of December 17, 2019. Greenfelder Supp. Dec. Ex. 10.

Plaintiff's Motion to Stay

GOJO filed its motion to stay this Southern District of New York action after IBD and Cozean moved to dismiss the FDA Action, but before Judge Carter denied it. Although Plaintiff initially sought a stay "pending resolution of the FDA Action," Pl.'s Mem., Dkt. 222, at 3, Plaintiff modified its request in Reply to instead seek a "tiered stay" that would terminate either at the end of the FDA Action, should IBD and Cozean prevail on their motion to dismiss, or six months after the motion in the FDA Action was denied. Reply, Dkt. 226, at 9. Plaintiff later supplemented its briefing to update the Court regarding Judge Carter's denial of IBD and Cozean's motion to dismiss the FDA Action. Dkt. 231. In the Supplemental Brief, Plaintiff renews its request that the Court "stay this case pending the outcome of the FDA Action." Pl.'s Supp. Mem., Dkt. 231, at 5. Since Plaintiff's tiered approach is now moot, the Court considers only Plaintiff's request to stay this action pending "resolution" of the FDA Action.

DISCUSSION

I. Legal Standards

A. Primary Jurisdiction Doctrine

Where an action "requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body," the primary jurisdiction

doctrine may be applicable. *In re KIND LLC "Health and All Natural" Litigation*, 209 F.Supp.3d 689, 693 (S.D.N.Y. 2016). The primary jurisdiction doctrine aims to promote "proper relationships between the courts and administrative agencies charged with particular regulatory duties," *Ellis v. Tribune Television Co.*, 443 F.3d 71, 81 (2d Cir. 2006) (quoting *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63, 77 S.Ct. 161, 1 L.Ed.2d 126 (1956)), and "to allocate initial decision-making responsibility between courts and agencies [] to ensure that they do not work at cross-purposes." *In re KIND LLC*, 209 F. Supp. 3d at 693. The doctrine is "rooted in part in judicial efficiency," *id.* (quoting *United States v. Philip Morris USA Inc.*, 686 F.3d 832, 838 (D.C.Cir. 2012)), but "relatively narrow in scope." *Segedie v. Hain Celestial Grp., Inc.*, No. 14-CV-5029 NSR, 2015 WL 2168374, at *13 (S.D.N.Y. May 7, 2015) (internal quotation omitted). Where applicable, "a court defers to the agency for advisory findings and either stays the pending action or dismisses it without prejudice, being careful not to disadvantage either party." *Petrosino v. Stearn's Prod., Inc.*, No. 16-CV-7735 (NSR), 2018 WL 1614349, at *10 (S.D.N.Y. Mar. 30, 2018) (citing *Johnson v. Nyack Hosp.*, 86 F.3d 8, 11 (2d Cir. 1996) (internal quotation omitted)).

Courts deciding whether to apply the primary jurisdiction doctrine in this Circuit consider four factors:

> (1) whether the question at issue is within the conventional experience of judges or whether it involves technical or policy considerations within the agency's particular field of expertise; (2) whether the question at issue is particularly within the agency's discretion; (3) whether there exists a substantial danger of inconsistent rulings; and (4) whether a prior application to the agency has been made.

Ellis, 443 F.3d at 81. In weighing these factors, the Second Circuit has further instructed courts to "balance the advantages of applying the doctrine against the potential costs resulting from complications and delay in the administrative proceedings." *Id.* at 83.

B. Motion to Stay

Even absent an administrative agency conflict, courts have the authority to stay proceedings pending the disposition of another case that could affect the outcome. *See Goldstein v. Time Warner N.Y. City Cable Group*, 3 F.Supp.2d 423, 437-38 (S.D.N.Y. 1998). Indeed, the power to stay a proceeding is a discretionary one, "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936); *see also Credit Suisse Sec. (USA) LLC v. Laver*, No. 18 CIV. 2920 (AT), 2019 WL 2325609, at *2 (S.D.N.Y. May 29, 2019). Still, "[a] stay is an intrusion into the ordinary processes of administration and judicial review," *Maldonado-Padilla v. Holder*, 651 F.3d 325, 328 (2d Cir. 2011) (quoting *Nken v. Holder*, 556 U.S. 418, 433-34 (2009)), to be granted only in "rare circumstances." *Landis*, 299 U.S. at 255.

> In deciding whether to stay proceedings, courts in this Circuit consider:
>
> (1) the private interests of the [nonmovant] in proceeding expeditiously with the civil litigation as balanced against the prejudice to the [nonmovant] if delayed; (2) the private interests of and burden on the [movant]; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest.

Readick v. Avis Budget Grp., Inc., No. 12 CIV. 3988 PGG, 2014 WL 1683799, at *2 (S.D.N.Y. Apr. 28, 2014) (quoting *Kappel v. Comfort*, 914 F.Supp. 1056, 1058 (S.D.N.Y.1996)).[3] "The party requesting a stay bears the burden of showing that the circumstances justify an exercise of [the Court's] discretion." *Nken*, 556 U.S. at 433-34.

[3] Defendant relies instead on a three-factor test articulated in *Firepass IP Holdings, Inc. v. Airbus Americas, Inc.*, No. 09-CV-4234 ENV LB, 2011 WL 2650484, at *1 (E.D.N.Y. July 6, 2011). Since that test appears limited to the patent context, *see id.* ("[d]eciding whether to stay litigation pending PTO reexamination turns on three factors…), the Court declines to apply it here.

II. The Primary Jurisdiction Doctrine is Inapplicable

Addressing the primary jurisdiction doctrine test first, all factors weigh against staying this case. As for the first factor, the claims and counterclaims at issue in this case center on whether statements made by the parties were false or misleading, in violation of the Lanham Act and relevant New York and California laws.[4] Such claims are routinely identified as properly within the realm of the judiciary. *See In re Frito-Lay N. Am., Inc. All Nat. Litig.*, No. 12-MD-2413 RRM RLM, 2013 WL 4647512, at *8 (E.D.N.Y. Aug. 29, 2013)("This case is far less about science than it is about whether a label is misleading, and the reasonable-consumer inquiry upon which some of the claims in this case depends is one to which courts are eminently well suited, even well versed."); *Jones v. ConAgra Foods, Inc.*, 912 F.Supp.2d 889, 898 (N.D.Cal.2012); *see also Ackerman v. Coca–Cola Co.*, No. 09–CV– 0395, 2010 WL 2925955, at *14 (E.D.N.Y. July 21, 2010) ("The question whether defendants have violated FDA regulations and marketed a product that could mislead a reasonable consumer is one courts are well-equipped to handle, and is not an appropriate basis for invoking the primary jurisdiction doctrine."); *Lockwood v. ConAgra Foods, Inc.*, 597 F.Supp.2d 1028, 1035 (N.D.Cal.2009) ("[E]very day courts decide whether conduct is misleading.").

The second factor also weighs against a stay because nothing in this action raises an *unresolved* question of FDA discretion. Of the four claims and four counterclaims at issue in this action, only a single claim even arguably turns on an interpretation of FDA law—IBD's counterclaim that GOJO made false or misleading statements about its Zylast sanitizers, including

[4] Generally, to establish a false advertising claim under Section 43(a) of the Lanham Act, a plaintiff must prove: (1) the defendant made a false or misleading representation; (2) that the representation actually deceived/has capacity to deceive substantial portion of intended audience; (3) that the deception is material; and (4) that there is a likelihood of injury. *See Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 177–78 (S.D.N.Y. 2004).

that Zylast products do not comply with FDA regulations. Obviously, a finding in the FDA Action that IBD's products do in fact violate the FDCA would substantially undermine IBD's ability to argue the falsity of that charge here. But GOJO's use of this single counterclaim to advocate a stay on the basis of agency expertise and deference confuses the inquiry. The FDA has already taken a clear position regarding the legality of IBD's sales of certain Zylast products under the FDCA. This Court is aware of that position and, to the minimal extent that position becomes relevant to the claims and counterclaims at issue here, will afford it the appropriate level of deference the law requires. What remains to be decided in the FDA Action, just like here, is in the hands of a federal district court.

The third and fourth factor also weigh against a stay. There is little to no risk of inconsistent results because the claims here do not require a finding as to whether IBD's products violate the FDCA, the sole issue in the FDA Action. As already noted, this action is brought under the Lanham Act, not the FDCA, and seven of the eight claims and counterclaims are in no way affected by the outcome of the FDA Action. As for IBD's counterclaim, there remains no risk of inconsistent results between this Court and *the FDA,* as this Court is aware of the FDA's settled position. Regarding the fourth factor, the FDA has made no indication that any additional action or guidance regarding IBD or hand sanitizer products—beyond seeking an injunction in the FDA Action—is forthcoming. Thus, awaiting FDA guidance on any issue relating to this action may mean waiting forever. The Court rejects GOJO's invocation of the primary jurisdiction doctrine for an Article III *judicial* proceeding as plainly inapplicable.[5]

III. The *Kappel* Factors Weigh Against a Stay

[5] This case is clearly distinguishable from *In re KIND LLC "Healthy & All Natural" Litig.*, 209 F. Supp. 3d 689, 693 (S.D.N.Y. 2016), a case relied upon by GOJO in support of a stay. In *In re Kind LLC*, the FDA had already commenced a rulemaking to address the exact labeling phrase being challenged in the litigation—the meaning of "all natural." *Id.* at 696. Here, by contrast, there is no indication that guidance by the FDA is in any way contemplated or forthcoming.

Moving on to assess GOJO's motion under the *Kappel* factors, the Court's finding that the FDA Action is irrelevant to most of the claims at issue here similarly counsels against granting a stay, particularly in light of the substantial prejudice facing IBD in further delay.

As the movant, GOJO bears the burden of demonstrating the need for a stay. Notably absent from its briefing, however, is any articulation of any prejudice *it* faces—as opposed to the court or the public—should this action and the FDA Action proceed simultaneously. The sole harm GOJO points to is damages. According to GOJO, denying a stay risks the "unjust and incongruous result" that IBD will be awarded damages for lost sales of products in this action which the FDA Action later determines were not able to be sold. GOJO Mem. at 11-12. But this argument fails because the feared result will never come to fruition. Even assuming the FDA prevails in the FDA Action, the FDA seeks only *prospective* injunctive relief preventing *future* sales of certain IBD products until IBD obtains a new drug application, abbreviated new drug application, or investigational new drug application. Greenfelder Dec. Ex. 3 at 10. The FDA is not seeking declaratory relief stating that IBD could not sell its products, that IBD's products are a new drug that could not be sold, or anything similar. Thus, GOJO's exposure to damage liability in this Lanham Act action will not be affected.

IBD's potential prejudice, however, is substantial. The parties in this action are business competitors, both of whom claim that the other's marketing practices are deceptive and causing them commercial harm. And while IBD has stipulated to stop some of its challenged marketing practices pending resolution of this action, GOJO has not. *See* Stip. and Order of Prel. Inj. on Consent, Dkt. 32. Since GOJO's conduct, alleged to be unlawful and commercially harmful, continues unrestrained until this action is resolved, IBD's interest in a speedy resolution of this action is strong and compelling. Moreover, although a trial date has been set in the FDA Action,

trials get postponed and verdicts get appealed. This case is already in its fifth year. Staying this action pending "resolution" of the FDA Action only increases the already real risk that witnesses' memories are fading and evidence is becoming stale. *See Howard v. Gutterman*, 3 B.R. 393, 394 (S.D.N.Y. 1980).

GOJO's application also fails to account for the prejudice of Hotan Barough. Although not a party in this action, Barough is a party in a separate lawsuit filed by GOJO in the U.S. District Court for the Central District of California on August 10, 2017 (Case No. 8:17-cv-01382) (the "Barough Action"). Matsuishi Decl., Dkt. 225, Ex. E. The claims in the Barough Action largely mirror the claims at issue here apart from the additional allegation that Barough was acting as IBD's agent. *Id.* Recognizing this overlap, the court presiding over the Barough Action has stayed the Barough Action pending resolution of this action. Matsuishi Decl. Ex. F. Thus, granting a stay in this action risks not only prejudice to IBD, but also to Barough, who cannot defend himself against GOJO's claims until this action is definitively resolved.

In light of all this prejudice, GOJO's appeals to the public interest (based on a purported need to defer to agency expertise) and the court's interest are unavailing. As already noted, a judgment on GOJO's and IBD's Lanham Act claims in this action will have no effect on the FDA's regulatory authority under the FDCA. The implication that the FDA's interests would somehow be hindered if a stay is not granted is simply not so.[6] As for the court's interest, the absence of overlapping issues similarly counsels against a stay. *See Aukema v. Chesapeak Appalachia, LLC*, 839 F. Supp. 2d 555, 559-61 (N.D.N.Y. 2012) (judicial economy not promoted where there is a lack of common issues between proceedings); *Motorola, Inc. v. Abeckaser*, No. 07-CV-3963 CPS/SMG, 2009 WL 816343, at *3 (E.D.N.Y. Mar. 26, 2009)("a court's interest is usually best

[6] It is notable that to date, the Court has not received any indication from the FDA or DOJ that it takes a position on GOJO's motion to stay this S.D.N.Y action.

served by discouraging motions to stay . . . . Courts have an interest in managing their cases and efficiently resolving litigation.").

CONCLUSION

GOJO's motion to stay this proceeding pending resolution of the FDA Action is DENIED. The Clerk of the Court is directed to close the motion at Dkt. 221.

Dated: New York, New York
September 16, 2019

SO ORDERED

PAUL A. CROTTY
United States District Judge